

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460




United States
Environmental Protection
Agency


Office of Pesticide Programs

MEMORANDUM

8/16/2018

SUBJECT: Acute Toxicity Review for Magna-Bon Pro-Teck, EPA Reg. No.: 66675-4

FROM: Ian Blackwell, M.S., Biologist 
Chemistry and Toxicology Team (CTT)
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny Tao, Senior Scientist/Team Leader (Acute Toxicology) 
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff, PM Team 31 / Tara Flint
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Magna-Bon II, LLC		
Decision No.: 541251	Submission No.: 1019886	E-Sub No.: None
DP No.: 447924		Action Code: A570
MRID No(s): 47950601 – 47950603, 41394801		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
024401	7758-99-8	Copper Sulfate Pentahydrate	19.8
		Other Ingredients	80.2
		Total	100.0

- I) **BACKGROUND:** The registrant, Magna-Bon II, LLC, has submitted an application to support a label amendment for their product: *Magna-Bon Pro-*

Teck, EPA Reg. No. 66675-4. The registrant has submitted a set of four acute toxicity studies in order to change the existing precautionary labeling of this product.

II) **FINDINGS/RECOMMENDATIONS:** In a 1/9/2009 (EPA)SRRD/PRB review, the focus product, Reg. No. 66675-4, was assigned the following acute toxicity profile:

Study	Toxicity Category	Status
Acute Oral Toxicity	III	Cited
Acute Dermal Toxicity	I	Waived
Acute Inhalation Toxicity	IV	Cited
Primary Eye Irritation	I	Waived
Primary Skin Irritation	I	Waived
Dermal Sensitization	Nonsensitizer	Waived

The waivers were granted for four acute toxicity endpoints, including acute dermal toxicity, eye and skin irritation, and skin sensitization, due to the product having a pH less than two. Three of these endpoints were assigned toxicity category I due to the reported pH of the subject product at that time.

For this current submission (DP Barcode 447924), the registrant has cited four acute toxicity studies (870.1200 through 870.2500) assigned MRID numbers 47950601 – 47950603 and 41394801. These studies were conducted in 2008 and 2009; but, were apparently never reviewed by the Agency. The dermal sensitization study was reviewed by the Chemistry and Toxicology Team (CTT) on 1/3/2018 for EPA File Symbol 92686-R. The registrant wants to base the product's precautionary labeling on actual acute toxicity data derived from testing the product itself rather than pH-based waivers.

III) **RECOMMENDATIONS:**

- 1) **Acute Oral Toxicity**: CTT will continue the toxicity categorization of the acute oral toxicity study from the 1/9/2009 review.
- 2) **Acute Dermal Toxicity**: The acute dermal toxicity study is acceptable is assigned toxicity category IV.
- 3) **Acute Inhalation Toxicity**: The acute inhalation toxicity study is acceptable and is assigned toxicity category IV.
- 4) **Primary Eye Irritation**: The primary eye irritation study is acceptable and is assigned toxicity category I.
- 5) **Primary Skin Irritation**: The primary skin irritation study is acceptable and is assigned toxicity category III.
- 6) **Dermal Sensitization**: CTT continues the waiver of the dermal sensitization study from the 1/9/2009 PRB/SRRD review.
- 7) The acute toxicity profile of Magna-Bon Pro-Teck, EPA Reg. No. 66675-4 is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Unknown	III	Cited
Acute Dermal Toxicity	47950601	IV	Accepted
Acute Inhalation Toxicity	47520603	IV	Accepted
Primary Eye Irritation	47950602	I	Accepted
Primary Skin Irritation	47950603	III	Accepted
Dermal Sensitization	Unknown	Nonsensitizer	Waived

IV) PRODUCT LABELING

1. Signal Word: DANGER
2. The statement, "Keep Out of Reach of Children (KOROC)", is required. It should appear immediately above the front-panel signal word "DANGER".

3. The Agency's Label Review Manual

(<https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf>) designates the following human-hazard

precautionary statements:

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Remove and wash contaminated clothing before reuse."

4. First Aid Statements:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

If Swallowed:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center, doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

This product meets the Agency requirements for Restricted-Use Classification based on information that places it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

Based upon information placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP *in addition to* Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions.

Note to PM/CRM/Registrant: The following statements are suggested types of information that may be included, if applicable"

- technical information on symptomatology;
- of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200)

Product Manager: 31
MRID No.: 47950601

Reviewer: I. Blackwell
Study Completion Date: 12/18/2009
Lab Study No.: 28293

Testing Laboratory: Eurofins| Product Safety Laboratories

Author: S. Dana Oley, B.A.

Quality Assurance (40 CFR §160.12): Included

Test Material: Magna-Bon Pro-Teck; "Clear blue liquid"

Species: Sprague-Dawley derived albino rat

Weight: Males= 302-355g

Age: 9-10 weeks

Females= 215-243 g

Source: Ace Animals, Inc.

Summary:

- LD₅₀ (mg/kg):**

Males	> 5,000 mg/kg b.w.
Females	> 5,000 mg/kg b.w.
Combined	> 5,000 mg/kg b.w.
- The estimated LD₅₀ is greater than 5,000 mg/kg of body weight.
- Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviation from §870.1200): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000	0/5	0/5	0/10

Observations: Anogenital staining, erythema at dose site, mechanical damage from patch removal, scabbing on back.

Gross Necropsy Findings: The lab reported no gross abnormalities.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (870.1300)

Testing Laboratory: Eurofins | Product Safety Laboratories

Product Manager: 31

Reviewer: I. Blackwell

MRID No.: 47520603

Study Completion Date: 9/18/2008

Lab Study No.: 25507

Author: George E. Moore, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Pro-Teck, "Clear, blue liquid", pH 2.05.

Concentration: nose-only exposure: grav.= 2.10 mg/L, nom.= 38.41 mg/L

Species: Sprague-Dawley derived albino rat

Weight: Males= 355-381 g

Females= 224-251 g

Age: 10-11 weeks

Source: Ace Animals Inc.

Summary:

- LC₅₀ (mg/L)**
Males > 2.10
Females > 2.10
Combined > 2.10
- The estimated LC₅₀ is greater than 2.10 mg/L of air.**
- MMAD:** 2.4 μ m
- Toxicity Category:** IV **Classification:** Acceptable

Procedure (Deviation from §870.1300): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.10 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < 4.7 µm
2.10 mg/L	2.4 µm	1.95 µm	82.95%

Chamber Environment	
Chamber Volume	6.7 liters
Airflow	25.6-25.8 LPM
Temperature	20-22° C
Relative Humidity	67-68%

Clinical Observations: The lab observed no clinical observations (ailments).

Gross Necropsy Findings: There were no gross abnormalities.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400)

Product Manager: 31
MRID No.: 47950602
Reviewer: I. Blackwell
Study Completion Date: 12/18/2009
Lab Study No.: 28294
Testing Laboratory: Eurofins | Product Safety Laboratories
Author(s): S. Dana Oley, B.A.

Quality Assurance (40 CFR §160.12): Included

Test Material: Magna-Bon Pro-Teck; "clear, blue liquid"

Dosage: 0.1 mL

Species: New Zealand White albino rabbit **Sex:** 3 male
Weight: Not reported **Age:** "young adult"
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** I
2. **Classification:** Acceptable

Procedure (Deviations from §870.2400): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	3/3	3/3	3/3	3/3	3/3	2/3	2/3	1/3
Iritis	3/3	3/3	3/3	3/3	3/3	3/3	2/3	1/3
Conjunctivae								
Redness	3/3	3/3	3/3	3/3	3/3	3/3	2/3	1/3
Chemosis	3/3	3/3	3/3	3/3	3/3	3/3	1/3	1/3
Discharge	3/3	3/3	3/3	3/3	3/3	3/3	2/3	1/3

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (870.2500)

Product Manager: 31
MRID No.: 47950603
Reviewer: I. Blackwell
Study Completion Date: 12/18/2009
Lab Study No.: 28295

Testing Laboratory: Eurofins | Product Safety Laboratories
Author: S. Dana Oley, B.A.

Quality Assurance (40 CFR §160.12): Included

Test Material: Magna-Bon Pro-Teck; "clear, blue liquid"
Dosage: 0.5 mL

Species: New Zealand Albino rabbit
Weight: Not reported
Source: Robinson Services, Inc.
Age: "young adult"

Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

Procedure (Deviations from §870.2500): None

Results: One hour after exposure to the test material, 3/3 animals displayed well-defined erythema, 2/3 slight edema and 1/3 very slight edema. One and two days after exposure, 2/3 had well-defined erythema, 1/3 very slight erythema, and, 3/3 had very slight edema. Three days (seventy hours) after exposure, 2/3 had very slight erythema with no edema. On Day 7 of the study, there was no erythema or edema reported.

Special Comments: None